REMARKS

Claim 1 has been amended to specify that the pharmaceutical agent is selected from the group consstting of an antibiotic, an anti-bacterial agent, and/or an anti-inflammatory agent. Support for this amendment can be found in paragraphs 52 and 26.

Rejection of Claims Under 35 U.S.C. 112

Claims 1-26 and 28-31 stand rejected under 35 U.S.C. 112 for allegedly being indefinite. Claim 1 has been amended to provide antecedent basis for the term "melt-processing temperature." Applicants therefore request withdrawal of this objection.

Rejection of Claims Under 35 U.S.C. 102

Claims 1-4 stand rejected under 35 U.S.C. 102 for allegedly being anticipated by U.S. Patent No. 6,406,498 to Tormala (the '498 patent). Applicants traverse this rejection. The Examiner states that the '498 patent teaches a pharmaceutical agent that is capable of retaining its solid particulate form in the melt-processing temperature of the matrix. Claim 1 has been amended to recite that the pharmaceutical agent is an antibiotic, an anti-bacterial agent, and/or an anti-inflammatory agent. The only portion of the '498 patent that mentions any of these specific pharmaceutical agents is col. 6, lines 31-40 and this section mentions antibiotics (and not anti-bacterial or anti-inflammatory agents). Therefore, the below discussion will focus only on antibiotics described in the '498 patent. No specific antibiotics are mentioned in the '498 patent and there is no description of the described antibiotics being capable of retaining their solid particulate form in the melt-processing temperature of the polymer matrix such that cavities are induced around the solid particles. Further, there is no basis for believing that the described antibiotics in the '498 patent inherently have this property.

As explained in the attached declaration, there are antibiotics with different melting (or decomposition) temperatures. The present claims are directed to those antibiotics whose melting temperatures are higher than the melt-processing temperatures of the polymer matrix in which the antibiotics are dispersed. Such antibiotics do not dissolve or melt during the melt-processing of the polymer matrix, which allows cavities to form around the antibiotics. If the antibiotics

melt or dissolve during the melt-processing of the matrix in which they are dispersed, there will be no cavities around the antibiotics (the antibiotics will be gone). Only if the antibiotics are capable of retaining their solid particulate form in the melt-processing temperature of the polymer matrix will cavities form. There is no teaching or suggestion in the '498 patent of such antibiotics. Similarly, there is no teaching or suggestion in the '498 patent of selecting a polymer matrix whose melt-processing temperature is lower than the melt-processing temperature of the antibiotics used. This point is clearly spelled out in the specification where it states: [t]he pharmaceutical agent (anti-bacterial agent, anti-inflammatory agent, etc.) should retain its solid particulate form in the melt-processing temperature of the matrix because of its melting temperature being higher than the melting temperature of the matrix." (Page 12, lines 24-27) .

Thus the present claims require a particular selection of pharmaceutical agents and polymer matrix—i.e. the melt-processing temperature of both elements must be considered such that the pharmaceutical agents do not dissolve in the polymer matrix so that cavities can form around the pharmaceutical agents. There is absolutely no teaching or suggestion in the '498 patent of selecting a polymer and a pharmaceutical agent that have melt-processing temperatures such that the pharmaceutical agents retain their solid form in the melt-processing temperature of the polymer matrix in which they are dispersed. Further, there are no specific antibiotics mentioned (and no categories at all mentioned of anti-bacterial and anti-inflammatory agents) in the '498 patent such that it can be asserted that the '498 patent inherently describes antibiotics that have this property. As such, Applicants submit that claim 1 (and all claims that depend therefrom) are not anticipated by the '498 patent and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 103

Claims 1-26 stand rejected as being allegedly rendered obvious by EP 1157708 to Fischer ("Fischer") in view of the '498 patent. As stated above, the '498 patent does not describe pharmaceutical agents that are capable of retaining their solid particulate form in the melt-processing temperature of the polymer matrix in which they are dispersed and Fischer does not make up for this deficiency. As such, Applicants submit that claim 1 (and all claims that depend

therefrom) are not rendered obvious by the combination of Fischer and the '498 patent and Applicants request withdrawal of this rejection.

Conclusion

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees that are required in connection with the filing of this response are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

Respectfully submitted,

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